

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service Food and Drug Administration

Memorandum

Date:

From:

Division of Dietary Supplement Products, Office of Nutritional Products,

Labeling and Dietary Supplements, HFS-810

Subject:

75-Day Pre-market Notification of New Dietary Ingredients

To:

Dockets Management Branch, HFA-305

Subject of the Notification: (Sanqi) Panax notoginseng

Firm:

Cyber Store LLC

Date Received by FDA:

June 5, 2003

90-Day Date:

September 4, 2003

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day pre-market notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Attachments

RPT197

Janya Jacks





Food and Drug Administration College Park, Maryland 20740

AUG 2 0 2003

Mr. Yao (Eric) Huang General Manager Cyber Store LLC 77 Mangolia Avenue Apartment 32 Jersey City, NJ 07306

Dear Mr. Huang:

This is to inform you that the notification, dated January 11, 2003, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on June 5, 2003. This is a resubmission of your original notification dated January 11, 2003, to which we responded on May 12, 2003. Your current notification concerns the substance called <u>Panax notoginseng</u> Burk. (sanqi) that you intend to market as a new dietary ingredient in the "Notoginseng (Sanqi) Instant and Capsules" products.

The description of the "Instant" form of the dietary supplement in the notification states that 1.2 g of the sanqi extract will be present in a 5 g serving of the instant product. The notification recommends that 5 g of the instant product be diluted in 100 ml of liquid and consumed three times daily. The description of the "capsulated form" of the dietary supplement in the notification states that 296 mg of the sanqi extract will be present per capsule.

Under 21 U.S.C. 350b(a)(2), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing <u>Panax notoginseng</u> Burk.(sanqi), when used under the conditions recommended or suggested, will reasonably be expected to be safe. While your

notification adequately describes the level of the new dietary ingredient, <u>Panax notoginseng</u> Burk.(sanqi), in both the "Notoginseng (Sanqi) Instant and Capsules" products, your notification did not provide information regarding the conditions of use recommended or suggested for <u>Panax notoginseng</u> Burk.(sanqi), in the "Notoginseng (Sanqi) Capsules" product. In addition, your notification did not provide complete English translations of all submitted information which precludes accurate evaluation of your information.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that Panax notoginseng Burk.(sanqi) in the "Notoginseng (Sanqi) Instant and Capsules" products, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of June 5, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

Susan J. Walker, M.D.

Acting Division Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

January 11, 2003

Division of Standards and Labeling Regulations

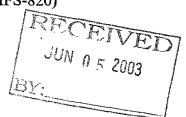
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)

Center for Food Safety and Applied Nutrition

Food and Drug Administration

5100 Paint Branch Parkway

College Park, MD, 20740-3835



Re: Marketing dietary ingredients under Supplement Health and Education Act.

Cyberstore LLC is requesting marketing clearance for its Sanqi(a Chinese edible herb)
Instant and Capsules. The pre-market notification information required by FDA's Office of Special Nutritional is as follows:

- a. Classification name: Notoginseng(Sanqi) Instant and Capsules
 Latin binomial name: panax notoginseng(Burk) F.H.Chen
 Common/Usual Name: Sanqi instant and Capsules
- b. Classification: Dietary supplements and their ingredients are governed and regulated under the Dietary Supplement Health and Education Act. Pursuant to Section 8 of the Act such dietary supplements must reasonably be expected to be safe. In consideration of the provisions of this new legislation, Cyberstore LLC. desires to import Notoginseng(sanqi) Instant and Capsules for use as a dietary ingredient in dietary supplements and as a standardized dietary supplement product. The product has passed the acute toxicity test in China and proved to be safe. The product also get the permission to be sold in Japan, Indonesia, Philippine. It all proved that it is reasonably be expected to be safe.

84629

- c. Label/Lebeling/Advertisements: Draft copies of the package labeling and promotional material, acute toxicity test report for Notoginseng instant and Capsules are enclosed as Exihit 2.
- d. Certifications: The product is produced by Yunnan Xin Yun Sanqi Industrial Co., Ltd. Complies with the requirements of Chinese Good Manufacturing Practice for health food. (See the attachment for the original copy of Sanitary Supervise Official Dispatch of People's Republic Of China and the Permission for marketing this product as dietary supplements in China and The Report of Examination issued by Chinese government to show the product is safe to human beings).

We would appreciate your earliest attention to this submission. The Notoginseng(sanqi) Instant and Capsules will not be marketed in U.S market until we receive FDA clearance of our submission or upon the expiration of 75 days from this submission.

Sincerely yours,

Yao(Eric) Huang, MBA

General Manager

Cyberstore LLC

77 mangnolia Ave. apt 32, Jersey City, NJ 07306, USA(212)723-2093

附件Attachment:

新云三七食品标签

Xin Yun Notoginseng Food Label:

1. 速溶饮料 Instant Drink

Ingredient pe		克溶于 100 毫升水 ve(5g) uted(100ml)	每 100 克产品百分比 100g formulas percent			
乳糖 Lactose		3.25	55			
三七提取物 notoginseng extract		1.2	24			
菊花提取物 chysanthemum extract		0.535	10.7			
阿斯巴甜 aspartame		0.015	0.3			

2. 胶囊 Capsules

配料 Ingredient	每粒胶囊 per capsule (370mg)	每 100 克产品百分比 100g formulas present
二七提取物 notoginseng extract	296mg	80
菊花提取物 chysanthemum extrac	ct 74mg	20

The report of product quality's analysis

Serial number: Food 01055

The sample's name: Xin Yun Notoginseng Instant

quantities:1000g/boxX3batches

Sample's mark: 20010309, 20010312, 20010315

sample's form: solid

Sample from: Yunnan Xin Yun Sanqi Industrial Co, LTD.

For the poupose: apply for the healthful food

Date of sample issued: 2001/03/29

Date of report: 2001/08/14

The standard of examination: GB 5009-85 GB/T 5009-1996 GB 4789-94

Main equipments: AA---670 atom--- absorbed and light -divided appearance, 721 meteorological

Chromatograph appearances, F-721 mercury—examining appearance.

Hygienic examination

Sample's number	· · · · · · · · · · · · · · · · · · ·				
Test items	20010309	20010312	20010315		
Pb(mg/kg)	Not found	Not found	Not found		
As(mg/kg)	0.20	0.17	0.18		
Hg(mg/kg)	Not found	Not found	Not found		
Moisture(%)	3.4	3.5	3.9		
Dust(%)	0.23	0.23	0.23		
Total saponins (%)	0.75	0.75	0.74		
Bacterium Total (%)	< 10	< 10	< 10		
Colon bacillus	< 30	< 30	< 30		
Mold	Not found	Not found	Not found		
Saccharomycete	Not found	Not found	Not found		
Pathogenic bacteria	Not found	Not found	Not found		

Issued By: Yunnan province health & epidemic prevention Station

Inspection centre

PRODUCT SAFETY CERTIFCATION

Hereby is certified that the mentioned product—XinYun brand notoginseng, is safety, no toxic, never do harm to human body.

It is specialty certified.

Signed by:

Title: Q.A Manager

YUNNAN XNYUN SANQI INDUSTRIAL CO.,LTD

The report of examination

Serial number: Food 01055 quantities:1000g/boxX3batches

Sample's mark: 20010309,20010312, 20010315 sample's form: solid

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The sample's name: Xin Yun Notoginseng Instant

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Main equipments: AA---670 atom— absorbed and light -divided appearance, 721 meteorological

Chromatograph appearances ,F-721 mercury—examining appearance.

STABILITY TEST

Environmental condition of keeping warm: temperature: 37.C, relative humidity:75%

Constantly test for three months, once per month.

Inspect time	20010309			20010312			20010315					
	Before	Keep	Keep	Keep	Before	Keep	Keep	Keep	Before	Keep	Keep	Keep
	keep	Warm	Warm	Warm	keep	Warm	Warm	Warm	keep	Warm	Warm	Warm
	warm	One	Two	Three	warm	One	Two	Three	warm	One	Two	Three
Inspect item		months	Months	months		months	months	months		months	months	months
Pb(mg/kg)	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
As(mg/kg)	0.20	0.20	0.25	0.23	0.17	0.19	0.23	0.26	0.18	0.19	0.25	0.25
Hg(mg/kg)	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Moisture(%)	3.4	2.5	0.70	0.78	3.5	3.0	0.78	0.84	3.9	3.2	0.94	1.0
Dust(%)	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23
Total saponins(%)	0.75	0.77	0.75	0.75	0.75	0.75	0.74	0.76	0.74	0.75	0.75	0.76
Bacterium Total (%)	< 10	< 10	15	< 10	< 10	< 10	5	< 10	< 10	< 10	< 10	< 10
Colon bacillus	< 30	< 30	< 30	< 30	< 30	< 30	< 30	< 30	< 30	< 30	< 30	< 30
Mold	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Saccharomycete	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Pathogenic bacteria	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND

Issued by:

Yunnan province health & epidemic prevention Stati

Inspection centre

云南省卫生防疫站检验中心

2001年8月14日

CERTIFICATE

(TRANSLATION)

(2002) K. Z. W. Zi No. 2661

This is to certify that the duplicated copy attached hereto complies with the original *Free Sale Certificate*, (2001) No. 0053, issued to the Yunnan Xin Yun Sanqi Industrial Company Ltd by the Yunnan Provincial Bureau of Health on February 5, 2002, and that the seal of *Yunnan Provincial Bureau of Health* on the original is authentic.

Notary: Liu Rongchang Kunming Notary Public Office Yunnan Province The People's Republic of China March 22, 2002

中华人民共和国云南省卫生厅

YUNNAN PROVINCIAL BUREAU OF HEALTH OF

THE PEOPLE'S REPUBLIC OF CHINA

产品出口自由销售书

Free Sale Certificate

兹证明云南新云三七产业有限公司(其法定地址为:昆明市三市街 32 号) 生产下列产品:

We hereby certify that the under-mentioned product is manufactured by Yunnan Xin Yun Sanqi Industrial Company Ltd with legal address:32,Sanshi street,Kunming.

产品名称
(Name of Product)
新云三七速溶粉
Xin Yun Notoginseng

性质及特征
(Nature & Description)
速溶饮料
Drink of Quick & Dissolving

说明 Illustration: 新云三七速溶粉在我国批准为食品,而非药品生产销售。
Xin Yun notoginseng, is sold in the market and is not considered as a Medicine in the P.R.China.

上述产品符合有关标准,同意在境内外自由销售。后附产品食品标签。 The above-mentioned product has been proven and freely sold in conformity with the relevant Law. Attachment is the food label.





BADAN'PENGAWAS OBAT DAN MAKANAN

KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN Nomor: 0140/Reg/TI / 2002 Tentang

PERSETUJUAN PENDAFTARAN

Menimbang

bahwa berdasarkan hasil - penilaian mutu, kemmanan dan kemantaatan terhadap per pendanaran dengan semua kelengkapannya yang diajukuh oleh ; Importir - PT. S. Cahaya Mandiri - perlu diberikan surat kepulusan:

Mengingat

- Cahaya Mandiri perlu diberikan surat kepulusan:

 1. Peraturan Pemerintah No.72 tahun 1998, tentang Pengamanan Sediaan Farmas Kesebatan;
- Peraturan Pemerintah Nomor 17 fahun 2001 tentang Tarif Atas Jenis Peneriman Bukan Pajak;
- 3. Keputusan Presiden Nomor 103 talian 2001 tentang Kedudukan. Tugas. Kewenangan, Susunan Organisasi dan Tala Kena Lembaga Pemerintah Non Dep
- 4. Peraturan Menteri Kesehatan Nomor: 246/Men Kes/Per/V/1990 tentang La bidustri Obat Tradisional dan Pendattaran Obat Tradisional;
- 5. Peraturan Menteri Keschatan, No. 1297/Men.Kes/Pér/XI/1998 tentang Pereda Tradisional Impor.
- Keputusan Menteri Keschalan Nomor; 661/Menkes/SK/VII/1994 tentang Persyant Tradisional.

MEMUTUSKAN:

Menetapkan Pertama

Persenjuan Pendaftaran Produk di bawah ini :

Nama : Xinyun Notoginseng

Beutuk sediaan , : Granul

Remasan : Dus, 20 Sachet @ Syram

Nama Produsen : Yunnan Xin Yun Sangi Industrial Company.

Alumat Produsen : Kumming, China

Nama Pendaftar : PT. Superindo Cahaya Mandiri

Alamat : Jl. Komp. Ketapang Indah Blok B1/No.12A,

Jakarta Pusat.

dengan nomor pendaftaran

POM TI 024 405 631

Kedua

Persenjuan pendaftaran ini diberikan sesual dengan keteninan sebagaimana tercamurlampiran I(smu), yang merupakan bagian tak terpisahkan dari keputusan ini:

Ketiga

Penandaan siap dar sesuai yang telah disetujui hajus diserahkan selambat-lambanya bulan sejak tanggal ditetapkan dan pelanggaran terhadap ketentian ini dapat dikenakan

Keempat

pembandan persenjuan pendaftaran:

\$1. - •

Apabita ternyata nama produk tersebut diatas terbukti secara hukum ada pihak lain yaberhak menggunakan sebelum tanggal Surat Keputusan ini, maka nama produk dinyatakan batal.

Kelima

Persetujuan ini berlaku 5 (lima) tahun dan dapat dibatalkan jika tidak memenuhi persyaratan ketentuan yang berlaku:

Reenam

Keputusan ini berlaku sejak tanggal ditetapkan.

Jakarta, DEC 2002

BADAN PENGAWAS OBAT DAN MAKA

H.Sampurno N31: 140 087 747

Salinan Surat Keputusan an disampaikan kepada Yth.: Kepala Balai Besar POM di Jakarta.

CERTIFICATE

(TRANSLATION)

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Notary: Liu Rongchang Kunming Notary Public Office Yunnan Province The People's Republic of China March 22, 2002

中华人民共和国云南省卫生厅

YUNNAN PROVINCIAL BUREAU OF HEALTH OF

THE PEOPLE'S REPUBLIC OF CHINA

编号/NO [See] 5 , see] 日期/Date: Frorwary 6 , see]

产品出口自由销售书

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We hereby certify that the under-mentioned product is manufactured by Yunnan Xin Yun Sanqi Industrial Company Ltd with legal address:32,Sanshi street,Kunming.

产品名称
(Name of Product)
新云三七速溶粉

Xin Yun Notoginseng

性质及特征

(Nature & Description)

速溶饮料

Drink of Quick & Dissolving

说明 Illustration: 新云三七速溶粉在我国批准为食品,而非药品生产销售。
Xin Yun notoginseng, is sold in the market and is not considered as a Medicine in the P.R.China.

上述产品符合有关标准,同意在境内外自由销售。后附产品食品标签。 The above-mentioned product has been proven and freely sold in conformity with the relevant Law. Attachment is the food label.





BADAN'PENGAWAS OBAT DAN MAKANAN

KEPUTUSAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN

Nomer: 0140 / Reg /T1 / 2002 Tontang PERSETUJUAN PENDAFTARAN

Menimbang

bahwa berdasarkan hasil - penilaian mutu, keamanan dan kemanfaatan terhada pendaharan dengan semua kelengkapannya yang diajukan oleh : Importis 1 Cahaya Mandiri perlu diberikan surat kepulusan:

- Peraturan Pemerintah No.72 tahun 1998, tentang Pengamanan Sediaun Fa Kesebatan
- Petaturan Pemerintah Nomor 17 fahun 2001 tentang Tarif Atas Jenis Pener 2. Bukan Pajak;
- 3. Keputusan Presiden Nomor 103 tahun 2001 tentang Kedudukan, T Kewenangan, Susunan Organisasi dan Tala Kerja Lembaga Pemerintah Nor
- Peraturan Menteri Keschatan Nomor: 246/Men Kes/Per/V/1990 tentang Industri Obat Tradisional dan Pendaltaran Obat Tradisional; a-
- .5 Penduran Menteri Kesehatan No. 1297/Men.Kes/Pér/XI/1998 tentang Pe Tradisional Impor.
- Reputusan Menteri Keschalan Nomor: 661/Menkes/SK/VII/1994 tentang Pe Tradisional.

MEMUTUSKAN:

Menetapkan Perinna.

Persenjuan Pendaftaran Produk di bawah ini :

Nama Xinyun Notoginseng

Bentuk sediaan Granul

Kemasan Dus, 20 Sachet @ 5gram

Nama Produsen Yunnan Xin Yun Sanqi Industrial Comp

Alamat Produsen Kunning, China

Nama Pendaftar PT. Superindo Caltaya Mandiri

Alamat Jl. Komp. Ketapang Indah Blok B1/No.1

Jakarta Pusat.

dengan nomor pendaftaran

POM TI

Kedua

Persettijaan pendaftaran ini diberikan sesuai dengan ketentuan sebagaimana terelanıpiran I(satu). yang merupakan bagian tak terpisahkan dari keputusan ini;

Kêtiga

Penandaan siap edar sesuai yang telah disetujui harus diserujuan selambat-lamba bulan sejak tanggal ditetapkan dan pelanggaran terhadap kelentilah ini dapat diken

Keempar

pembandan persenjuan pendaharah: Apabila ternyata nama produk tersebut diatas terbukti secara hukum ada pihak lar berhak menggunakan sebelum tanggal Surat Keputusan ini, maka nama pro-

dinyatakan batal,

Persettijuan ini berlaku 5 (lima) tahun dan dapat dibatatkan jika tidak mementihi per

atau kerentuan yang berlaku:

Keputusan ini berlaku sejak tanggal ditetapkan.

Jakana, DEC 2002

BADAN PENGAWAS OBAT DAN MA

N312: 340 087 747

Salinan Sicrat Reputusan ini disampaikan kepada Yth: copala Balai Besar POM di Jalanta.

The report of examination

The serial number of report:0006

Sample name: notoginseng herbal tea

Serial number of sample: health 2006

Production date: 2001/3/9

Quantities: 7.0kg

The unit of sample issued: Yunnan Xin Yun Sangi industrial Co, Ltd.

Manufacturer: Yunnan Xin Yun Sanqi industrial Co, Ltd.

Date of sample issued:2001/4/2

Delivered by: Libin

Date of accept sample:2001/4/2

Exam Items:

- 1. The acute toxicity test on rat and mouse by raising them "Xin Yun notoginseng instant "
- 2. The test of bone marrow cell micro-nuclear and sperm's deformity on mouse.
- 3. Lopsided-caused
- 4. Big mice fed with Xin Yun notoginseng instant
- 5. Mouse typhus Salmonella and mammal particle body enzyme test

Technological standard: GB 15193.3-94. 4-94. 5-94. 7-94. 14-94.13-94 from The people's Republic of China.

The main test equipment: large-scale biomicroscope, the biochemical equipment .etc. The environmental condition for the test: room temperature 16° C--20° C, relative umidity:25%--55%.

Conclusion:

IIt has not caused animal's death, by giving rat and mouse enema with the dosage up to 15g/kg of Xin Yun notoginseng instant issued by Yunnan Xin Yun Sanqı industrial Co.Ltd .So it has been testified that Xin Yun notoginseng is safe and nonpoisonous according to the standard of acute toxicity and toxicity dosage.

- 2 As a result of no obvious difference between "test group" and "contrasted group". after the test of bone marrow mirco-nuclear and mouse's sperm's deformity. It indicates that Xin Yun notoginseng instant has no potential effect on causing sudden change and sperm lopsided.
- 3. From the test of causing lopsided by feeding mouse with Xin Yun notoginseng instant, no obvious difference have found between "solvent contrast group "and "the test group". The weight and height of Fetus are not unusual compared "test group" and "contrast group". And there are no remarkable disparity found from observing skeleton transparent and viscera sample.
- 4. We add Xin Yun notoginseng instant into fodder, feeding wistar mouse for 30 days When the amount of instant powder reach up to 3 times, 50times, and 100times respectively as the intaked amount of human beings daily, the animal's general physiological state is normal, and the behavior of animals has not found unusual. Neither poison nor death appear. Both blood index and biochemistry index is normal basically as well as the coefficient value of liver and kidney. On the view of pathology

histology, there are no obvious damaged-change in liver, kidney, stomach, twelve mean intestines, colon rectum organization. Taking the dosage of 156.25-10000 u g/ware of Xin Yun notoginseng instant, no positive displays on fungus. No matter we add S9,TA97,TA98,TA100,TA102 or not. Under this experiment, Xin Yun notoginseng instant has no function to cause sudden change.

Checking and technology: Liuaihua Verify:Heweishun Mainly

examine:wangruifang

Date of report: June 11,2001. Final revise date: June 18,2001.

公证书

中华人民共和国云南省昆明市公证处

SANITARY SUPEEVISE OFFICIAL DISPATCH OF THE PEOPLE'S REPUBLIC OF CHINA

D.W.S.J.Z.No. (2002) 024

Tel: (0871) 3625337

Company Name: Yunnan Xin Yun Sanqi Industrial Co., Ltd

Company Category: <u>Joint-venture</u>. Legal Representative: <u>Ji Wenfeng</u>

Address Registration: 32, Sanshi street, Kunming, China.

Supervise opinions:

This is to certify that "Xin Yun Notginseng Instant" produced by Yunnan Xin Yun Sanqi Industrial Co., Ltd, Complies with the requirements of Chinese Good Manufacturing Practices for health food, after censor to the produce process, produce place and products formulates. Three batch of sample are inspected by the Yunnan Sanitary Inspection Centre, are accord with the demands of General standard for food.

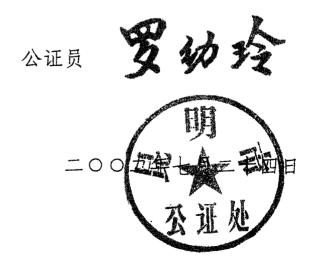


证 明 书

(2002) 昆证外字第 7612 号

兹证明前面的复印件与云南省卫生厅卫生监督 所于二〇〇二年七月十八日出具的 D.W.S.J.No.(2002)024 号英文本的《SANITARY SUPERVISE OFFICIAL DISPATCH OF THE PEOPLE'S REPUBLIC OF CHINA》的原件相符。原件上的"云南省卫生厅卫生监督所"的印鉴属实。

中华人民共和国云南省昆明市公证处



XX04758565

CERTIFICATE (TRANSLATION)

(2002) K. Z. W. Zi No. 7612

This is to certify that the duplicated copy attached hereto is in conformity with the original SANITARY SUPERVISE OFFICIAL DISPATCH OF THE PEOPLE'S REPUBLIC OF CHINA in English, D. W. S. J. Z No. (2002) 024, issued on July 18, 2002 by Yunnan Provincial Bureau of Health Branch of Sanitary Supervise. The seal of "Yunnan Provincial Bureau of Health Branch of Sanitary Supervise" affixed on the original is authentic.

Notary: Luo Youling Kunming Notary Public Office Yunnan Province The People's Republic of China July 24, 2002

XX04758577